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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,305	10/03/2001	Robert C. Brunham	1038-1153MIS	3368

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EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,305	BRUNHAM ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed September 8, 2006 is acknowledged and has been entered. Claims 1-18, 20, 21, 23 and 29-40 have been canceled. Claims 19, 22 and 24-28 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 19, 22 and 24-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 20, 22 and 24-28 of copending Application No. 10/699683. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an attenuated strain of a bacterium harbouring a vector (plasmid vector or pcDNA3/MOMP) comprising a nucleic acid molecule encoding a *Chlamydia* protein (i.e. major outer membrane protein (MOMP) of a strain of *Chlamydia* (or *C. trachomatis*) and a promoter sequence (cytomegalovirus promoter) operatively coupled to said nucleic acid molecule for expression of said protein by cells of a host to which the attenuated strain is administered but not by the attenuated bacteria (*Salmonella typhinmurium*).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This provisional obviousness-type double patenting rejection is maintained for the reasons of record. With regard to this rejection, Applicants did not set forth any arguments in the September 27, 2005 amendment.

4. Claims 19, 22, 24, 25, 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Murdin et al (6693087 or 6686339).

The applied reference has a common assignee (Aventis Pasteur Limited) and a common inventor (Andrew D. Murdin) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Murdin et al, for example 6693087, discloses a nucleic acid molecule encoding an outer membrane protein (MOMP) of a strain of *Chlamydia* (abstract). Murdin et al discloses expression cassettes, vectors and cells transformed or transfected with the polynucleotides (encoding the MOMP) of the invention (col. 4; claims). Murdin et al discloses methods for producing a polypeptide of the invention in a recombinant host system and related expression cassettes, vectors, and transformed or transfected cells; (ii) a live vaccine vector, such as a pox virus, *Salmonella typhimurium*, or *Vibrio chloerae* vector, containing a polynucleotide of the invention, such vaccine vectors being useful for, e.g., preventing the treating Chlamydia infection, in combination with a diluent or carrier, and related pharmaceutical compositions and associated therapeutic and/or prophylactic

methods (col. 4). Murdin et al discloses (i) an expression cassette containing a DNA molecule of the invention placed under the control of the elements required for expression, in particular under the control of an appropriate promoter; (ii) an expression vector containing an expression cassette of the invention; (iii) a procaryotic or eucaryotic cell transformed or transfected with an expression cassette and/or vector of the invention, as well as (iv) a process for producing a polypeptide or polypeptide derivative encoded by a polynucleotide of the invention, which involves culturing a procaryotic or eucaryotic cell transformed or transfected with an expression cassette and/or vector of the invention, under conditions that allow expression of the DNA molecule of the invention and, recovering the encoded polypeptide or polypeptide derivative from the cell culture. The recombinant expression system can be selected from procaryotic and eucaryotic hosts. Eucaryotic hosts include yeast cells (e.g., *Saccharomyces cerevisiae* or *Pichia pastoris*), mammalian cells (e.g., COS1, NIH3T3, or JEG3 cells), arthropods cells (e.g., *Spodoptera frugiperda* (SF9) cells), and plant cells. Preferably, a procaryotic host such as *E. coli* is used. (see cols. 10-11) Murdin et al discloses that elements for expression include a promoter suitable for expression in mammalian cells, such as a cytomegalovirus vector (see col. 12; col. 14). Murdin et al discloses attenuated *Salmonella typhimurium* strains genetically engineered for recombinant expression of heterologous antigens (see col. 13). The prior art anticipates the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' bacterium with the bacterium of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed bacterium and the bacterium of the prior

art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed September 8, 2006 have been fully considered but they are not persuasive. Applicants have asserted that 6693087 ('087) does not disclose a MOMP. Applicants have asserted that the protein of '087 is a quite different protein of Chlamydia. Applicants have asserted that 6686339 ('039) discloses an inclusion membrane protein C that is a different protein from MOMP. Applicants have enclosed for Examiner consideration a sequence comparison for the amino acid sequence from the MOMP, POMP91A and InC proteins of Chlamydia pneumoniae.

However, it is noted that none of the claims recite a specific nucleotide or amino acid sequence. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., amino acid sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not provide any characteristics or properties other than it is a MOMP. Further, the specification does not disclose or teach the MOMP amino acid sequence used in the sequence comparison. The pending specification only list 2 nucleic acid sequences on the Raw Sequence Listing.

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murdin et al (6693087 or 6686339) as applied to claims 19, 22, 24, 25, 27 and 28 above, and further in view of Brunham (WO 98/02546).

Murdin et al, for example 6696087, teaches a nucleic acid molecule encoding an outer membrane protein (MOMP) of a strain of *Chlamydia* (abstract). Murdin et al teaches expression cassettes, vectors and cells transformed or transfected with the polynucleotides (encoding the MOMP) of the invention (col. 4; claims). Murdin et al teaches methods for producing a polypeptide of the invention in a recombinant host system and related expression cassettes, vectors, and transformed or transfected cells; (ii) a live vaccine vector, such as a pox virus, *Salmonella typhimurium*, or *Vibrio chloerae* vector, containing a polynucleotide of the invention, such vaccine vectors being useful for, e.g., preventing the treating Chlamydia infection, in combination with a diluent or carrier, and related pharmaceutical compositions and associated therapeutic and/or prophylactic methods (col. 4). Murdin et al teaches (i) an expression cassette containing a DNA molecule of the invention placed under the control of the elements required for expression, in particular under the control of an appropriate promoter; (ii) an expression vector containing an expression cassette of the invention; (iii) a procaryotic or eucaryotic cell transformed or transfected with an expression cassette and/or vector of the invention, as well as (iv) a process for producing a polypeptide or polypeptide derivative encoded by a polynucleotide of the invention, which involves culturing a procaryotic or eucaryotic cell transformed or transfected with an expression cassette and/or vector of the invention, under conditions that allow expression of the DNA molecule of the invention and, recovering the encoded polypeptide or polypeptide derivative from the cell culture.

The recombinant expression system can be selected from procaryotic and eucaryotic hosts. Eucaryotic hosts include yeast cells (e.g., *Saccharomyces cerevisiae* or *Pichia pastoris*), mammalian cells (e.g., COS1, NIH3T3, or JEG3 cells), arthropods cells (e.g., *Spodoptera frugiperda* (SF9) cells), and plant cells. Preferably, a procaryotic host such as *E. coli* is used. (see cols. 10-11) Murdin et al teaches that elements for expression include a promoter suitable for expression in mammalian cells, such as a cytomegalovirus vector (see col. 12; col. 14). Murdin et al teaches attenuated *Salmonella typhimurium* strains genetically engineered for recombinant expression of heterologous antigens (see col. 13). Murdin et al teaches the claimed invention except for the specifically claimed plasmid vector pcDNA3/MOMP.

However, Brunham teaches DNA immunization against Chlamydia infection comprising nucleic acid, including DNA, immunization to generate a protective immune response in a host, to a major membrane protein of a strain of Chlamydia (*C. trachomatis*), preferably contains a nucleotide sequence encoding a MOMP that generates antibodies that react with MOMP and a promoter sequence operatively couples to the first nucleotide sequence for expression of the MOMP in the host (abstract; p. 3; pp. 20-21 Example 4). The non-replicating vector may be formulated with a pharmaceutically acceptable carrier for in vivo administration to the host (abstract; p. 3). Brunham teaches that the promoter may be the cytomegalovirus promoter and that the non-replicating vector may be plasmid pcDNA3 into which the nucleotide sequence is inserted (i.e. pcDNA3/MOMP) (pp. 4-5; p. 8). The plasmid vector containing the MOMP gene from *Chlamydia trachomatis* was pcDNA3 with transcription under control of the human cytomegalovirus promoter (pp. 16-17; p. 25, Table 2; claims). The prior teaches

the use of the promoters and vectors for expression of the Chlamydia MOMP for protecting a host against Chlamydia infection.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the attenuated *Salmonella typhimurium* bacteria of Murdin et al to include harboring a nucleic acid molecule encoding a Chlamydial protective MOMP of Brunham because Murdin et al teaches that through administration of a live attenuated bacteria that encodes the MOMP to a host is stimulated to produce a protective or therapeutic immune response to the MOMP (see col. 12). The person of ordinary skill in the art at the time the invention was made would have been motivated by the reasonable expectation of success of obtaining an attenuated *Salmonella typhimurium* bacteria that comprises the nucleic acid, plasmid and promoter of Murdin et al that encodes a protective MOMP of *Chlamydia trachomatis*, because both references teach the administration of the bacterium (having the nucleic acid sequence that encode the MOMP) to a host. The attenuated bacteria is capable of expressing a recombinant gene product, wherein use of a nucleic acid molecule that encodes a protective MOMP results in stimulating an immune response against the *Chlamydia trachomatis* MOMP. The claimed invention is prima facie obvious in view of the combined teachings of Murdin et al in view of taken with Brunham, in the absence of unexpected results or other convincing evidence to the contrary.

The rejection is maintained for the reasons of record. Applicant's arguments filed September 8, 2006 have been fully considered but they are not persuasive. Applicants have asserted that 6693087 ('087) does not disclose a MOMP. Applicants have asserted that the protein of '087 is a quite different protein of Chlamydia. Applicants have asserted that 6686339 ('039) discloses an inclusion

membrane protein C that is a different protein from MOMP. Applicants have enclosed for Examiner consideration a sequence comparison for the amino acid sequence from the MOMP, POMP91A and InC proteins of Chlamydia pneumoniae. Applicants have also asserted that neither '087 nor Brunham (WO 98/02546) provide any motivation to substitute the vectors of '087 for the vectors described in '087 in an attenuated bacterium environment.

However, it is noted that none of the claims recite a specific nucleotide or amino acid sequence. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., amino acid sequence) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not provide any characteristics or properties other than it is a MOMP. Further, the specification does not disclose or teach the MOMP amino acid sequence used in the sequence comparison. The pending specification only lists 2 nucleic acid sequences on the Raw Sequence Listing.

With regard to the motivation or suggestion to combine the references to make the claimed invention, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the attenuated *Salmonella typhimurium* bacteria of Murdin et al to include harboring a nucleic acid molecule encoding a Chlamydial protective MOMP of Brunham because Murdin et al teaches that through administration of a live attenuated bacteria that encodes the MOMP to a host is stimulated to produce a protective or therapeutic immune response to the MOMP (see col. 12). The person of ordinary skill in the

art at the time the invention was made would have been motivated by the reasonable expectation of success of obtaining an attenuated *Salmonella typhimurium* bacteria that comprises the nucleic acid, plasmid and promoter of Murdin et al that encodes a protective MOMP of *Chlamydia trachomatis*, because both references teach the administration of the bacterium (having the nucleic acid sequence that encode the MOMP) to a host. The attenuated bacteria is capable of expressing a recombinant gene product, wherein use of a nucleic acid molecule that encodes a protective MOMP results in stimulating an immune response against the *Chlamydia trachomatis* MOMP. The claimed invention is prima facie obvious in view of the combined teachings of Murdin et al in view of taken with Brunham, in the absence of unexpected results or other convincing evidence to the contrary.

6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
November 20, 2006